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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,232	07/22/2003	Nagy Adly Habib	380048-97	8627

7590 07/01/2009

Attn: Barbara A. Wrigley
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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
07/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,232	HABIB ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 37-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 12-19 and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent 5,472,441) in view of Edwards (U.S. Patent 5,836,906) in still further view of Swanson (U.S. Patent 6,267,760) and still in further view of Lennox et al. (U.S. Patent 5,919,191).

Regarding claims 1-6, 12-14, 19 Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of tissue to be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. It should be noted the mere application of electromagnetic energy to the tissue by the needle array creates a heat-treated tissue volume (having a desired length, width and depth). Edwards et al. clearly disclose at least two needles which define a radiation pattern having a localized power profile/distribution centered on the needles, which is interpreted as confining the heat-treated tissue volume (which coincides with the power profile/distribution), see 1110 of figure 11. Additionally, having the heat-treated tissue volume center coincide with the planned incision line is extremely well known and desirable, as the heat-treated tissue volume center/line of center is the point/line of maximum symmetry and therefore the

best location to place the incision. Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. fail to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. **Edwards et al. explicitly disclose "high-frequency currents are used in electrocautery procedures for cutting human tissue, especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated. The frequency of the current for this use must be above ca. 300 kHz in order to avoid any adverse nerve and/or muscle responses," see col. 1:42-55.** Additionally, Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Edwards discloses a tissue heating device having retractable needles (12) and teaches an alternative or equivalent energy delivery of microwave with cooling means and RF, see col. 1-7 and

particularly col. 7, lines 28-38 and figures 1-6. Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. **Lennox et al. disclose an electrosurgical device for tissue removal and teach coagulating tissue prior to resection in order "to effect substantially bloodless tissue removal which can reduce complications from blood loss, fluid absorption, time in surgery, and patient trauma," see col. 4:12-32. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Additionally, the examiner interprets "bloodlessly resecting the tissue from the body" as broadly equivalent to "severing the tissue from the body" without excessive bleeding.** Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al., as taught by Edwards, to use microwave (electromagnetic) energy as an alternate means of heating tissue, and as is well known in the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, and as taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue, and as is also well known to place the incision line at the center/line of center of the heat-treated tissue volume since that is the point/line of maximum heat-treated tissue volume symmetry and as finally taught by Lennox et al., to coagulate the tissue sufficiently in order to resect (sever from the body) the tissue bloodlessly.

Regarding claims 15-18, 28-31 and 33-35, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see Edwards et al. col. 6-14 and figure 16.

Regarding claims 25-27, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see Edwards et al. figures 1-16.

Regarding claim 32, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see the conducting wires connected to the needles of (Edwards I) in figures 1-16.

Claims 7-11 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent 5,472,441) in view of Edwards (U.S. Patent 5,836,906) in still further view of Swanson (U.S. Patent 6,267,760) and still in further view of Lennox et al. (U.S. Patent 5,919,191) as applied to claims 1, 3 and 6 above, and still further in view of admitted prior art.

Regarding claims 7-11 and 20-24 Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention in further view of Applicant's admission on the record that the claimed species are not patentably distinct as noted above.

Claims 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent 5,472,441) in view of Swanson (U.S. Patent 6,267,760) and further in view of Lennox et al. (U.S. Patent 5,919,191).

Regarding claims 37 and 40, Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of tissue to be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. It should be noted the mere application of electromagnetic energy to the tissue by the needle array creates a heat-treated tissue volume (having a desired length, width and depth). Edwards et al. clearly disclose at least two needles which define a radiation pattern having a localized power profile/distribution centered on the needles, which is interpreted as

confining/defining the heat-treated tissue volume (which coincides with the power profile/distribution), see 1110 of figure 11. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. fail to disclose to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. Finally, Edwards et al. fail to explicitly disclose bloodless resection of tissue. **Edwards et al. explicitly disclose "high-frequency currents are used in electrocautery procedures for cutting human tissue, especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated. The frequency of the current for this use must be above ca. 300 kHz in order to avoid any adverse nerve and/or muscle responses," see col. 1:42-55.**

Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the

heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. Additionally, having the heat-treated tissue volume and/or width straddle the planned incision line is inherent, as Swanson teaches incising within the heat-treated volume. **Lennox et al. disclose an electrosurgical device for tissue removal and teach coagulating tissue prior to resection in order "to effect substantially bloodless tissue removal which can reduce complications from blood loss, fluid absorption, time in surgery, and patient trauma," see col. 4:12-32. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Additionally, the examiner interprets "bloodlessly resecting the tissue from the body" as broadly equivalent to "severing the tissue from the body" without excessive bleeding.** Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al., as is well known in the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, as taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue, and as is also well known to place the incision line at the center/line of center of the heat-treated tissue volume since that is the point/line of maximum heat-treated tissue volume symmetry and as finally taught by Lennox et al., to coagulate the tissue sufficiently in order to resect (sever from the body) the tissue bloodlessly.

Regarding claim 38, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention as the tissue heat-treating device makes an ablation lesion locally and the device must be removed so that the lesion area is free to be incised.

Regarding claim 39, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see Swanson col. 8:33-41, col. 45:19-43.

Regarding claim 41, Edwards et al. disclose the claimed invention see figure 11.

Regarding claim 42, Edwards et al. disclose the claimed invention, see col. 3:11-28.

Regarding claims 43 and 44, Edwards et al. disclose the claimed invention, see col. 3 and figures 1-19.

Response to Arguments

Applicant's arguments, see page 3 of 13, 2nd full paragraph, filed 5/4/2009, with respect to the rejection(s) of claim(s) 1-35 and 37-44 under 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lennox et al. (U.S. Patent 5,919,191) that has a filing date of January 30, 1997 and qualifies as prior art given the August 4, 1998 priority date of

the presently claimed subject matter under question that is the "bloodless resection of tissue" or "severing of tissue without excessive bleeding."

The remaining Applicant argument/remark is that Edwards et al. and Swanson teach away from the combination. The examiner appreciates the review how a reference may teach away from another. However, both references coagulate soft tissue achieving some bloodless cutting/resecting/severing, but it is Swanson that explicitly teaches and discloses making the incisions to determine or achieve a desired coagulation and incision depth. Applicant appears to distinguishing the blunt tip coagulator of Swanson with the needle coagulators of Edwards et al. which is a bodily incorporation argument. That the feature of one reference cannot be physically incorporated into the primary reference does not render the combination of references improper. In re Nievelt, 482 F.2d 965, 179 USPQ 224 (CCPA 1973); In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549-50 (CCPA 1969). The issue is whether the prior art, taken as a whole, would have rendered the claimed subject matter obvious. In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991); In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Again and maybe most importantly, the examiner interprets "bloodlessly resecting the tissue from the body" as broadly equivalent to "severing the tissue from the body" without excessive bleeding.

Due to the RCE this action is made non final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/david shay/
Primary Examiner, Art Unit 3769